

ENZO BIOCHEM INC
Form 10-Q
December 08, 2015
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

Mark one

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended October 31, 2015

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 001-09974

ENZO BIOCHEM, INC.

(Exact name of registrant as specified in its charter)

New York
(State or Other Jurisdiction)

13-2866202
(IRS. Employer)

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

of Incorporation or Organization) Identification No.)
527 Madison Ave, New York, New York 10022
(Address of Principal Executive office) (Zip Code)

212-583-0100
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant has required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 45 of Regulation S-T (§232.405 of that chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit and post such files).

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.)

Yes No

As of December 2, 2015, the Registrant had approximately 46,069,000 shares of common stock outstanding.

ENZO BIOCHEM, INC.
FORM 10-Q
October 31, 2015

INDEX

PART I - FINANCIAL INFORMATION

| | |
|--|----|
| <u>Item 1. Condensed Financial Statements</u> | 3 |
| <u>Consolidated Balance Sheets – October 31, 2015 (unaudited) and July 31, 2015 (audited)</u> | 3 |
| <u>Consolidated Statements of Operations for the three months ended October 31, 2015 and 2014 (unaudited)</u> | 4 |
| <u>Consolidated Statements of Comprehensive Income (Loss) for the three months ended October 31, 2015 and 2014 (unaudited)</u> | 5 |
| <u>Consolidated Statement of Stockholders' Equity for the three months ended October 31, 2015 (unaudited)</u> | 6 |
| <u>Consolidated Statements of Cash Flows for the three months ended October 31, 2015 and 2014 (unaudited)</u> | 7 |
| <u>Notes to the Consolidated Financial Statements</u> | 8 |
| <u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | 17 |
| <u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u> | 27 |
| <u>Item 4. Controls and Procedures</u> | 27 |
| <u>Part II – OTHER INFORMATION</u> | |
| <u>Item 1. Legal Proceedings</u> | 28 |
| <u>Item 1A. Risk Factors</u> | 28 |
| <u>Item 6. Exhibits</u> | 28 |
| <u>Signatures</u> | 28 |

Part 1 Financial Information**Item 1** Financial Statements**ENZO BIOCHEM, INC.****CONSOLIDATED BALANCE SHEETS****(in thousands, except share data)**

| | October 31, 2015 (unaudited) | July 31, 2015 |
|--|------------------------------------|------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 30,642 | \$ 18,109 |
| Accounts receivable, net of allowances | 12,763 | 12,109 |
| Other accounts receivable | — | 6,650 |
| Inventories | 7,582 | 7,396 |
| Prepaid expenses and other | 1,780 | 2,222 |
| Total current assets | 52,767 | 46,486 |
| Property, plant and equipment, net | 8,132 | 7,948 |
| Goodwill | 7,452 | 7,452 |
| Intangible assets, net | 5,707 | 6,155 |
| Other assets | 338 | 353 |
| Total assets | \$ 74,396 | \$ 68,394 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Loan payable | \$ 3,013 | \$ 3,013 |
| Accounts payable – trade | 9,450 | 8,762 |
| Accrued liabilities | 12,357 | 11,297 |
| Other current liabilities | 969 | 886 |
| Total current liabilities | 25,789 | 23,958 |
| Deferred taxes | 37 | 37 |
| Other liabilities | 1,357 | 1,793 |
| Total liabilities | \$ 27,183 | \$ 25,788 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred Stock, \$.01 par value; authorized 25,000,000 shares; no shares issued or outstanding | — | — |
| Common Stock, \$.01 par value; authorized 75,000,000 shares; shares issued and outstanding: 46,068,816 at October 31, 2015 and 46,062,065 at July 31, 2015 | 461 | 461 |

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

| | | |
|--|------------|-----------|
| Additional paid-in capital | 325,077 | 324,966 |
| Accumulated deficit | (280,248) | (284,682) |
| Accumulated other comprehensive income | 1,923 | 1,861 |
| Total stockholders' equity | 47,213 | 42,606 |
| Total liabilities and stockholders' equity | \$ 74,396 | \$68,394 |

The accompanying notes are an integral part of these consolidated financial statements.

3

ENZO BIOCHEM, INC.**CONSOLIDATED STATEMENTS OF OPERATIONS****(UNAUDITED)****(in thousands, except per share data)**

| | Three Months Ended October 31, | |
|---|--------------------------------------|------------|
| | 2015 | 2014 |
| Revenues: | | |
| Clinical laboratory services | \$ 17,090 | \$ 15,822 |
| Product revenues | 7,687 | 8,002 |
| Royalty and license fee income | 400 | 1,000 |
| Total revenues | 25,177 | 24,824 |
| Operating expenses: | | |
| Cost of clinical laboratory services | 10,332 | 10,130 |
| Cost of product revenues | 3,611 | 3,695 |
| Research and development | 867 | 791 |
| Selling, general, and administrative | 10,225 | 10,285 |
| Provision for uncollectible accounts receivable | 704 | 541 |
| Legal fee expense | 1,601 | 2,466 |
| Legal settlements, net | (6,800) | — |
| Total operating expenses | 20,540 | 27,908 |
| Operating income (loss) | 4,637 | (3,084) |
| Other income (expense): | | |
| Interest | (40) | (69) |
| Other | 54 | 19 |
| Foreign exchange loss | (130) | (472) |
| Income (loss) before income taxes | 4,521 | (3,606) |
| Provision for income taxes | (87) | (123) |
| Net income (loss) | \$4,434 | \$(3,729) |
| Net income (loss) per common share: | | |
| Basic | \$0.10 | \$(0.08) |
| Diluted | \$0.10 | \$(0.08) |
| Weighted average common shares outstanding: | | |
| Basic | 46,068 | 44,564 |
| Diluted | 46,193 | 44,564 |

The accompanying notes are an integral part of these consolidated financial statements.

ENZO BIOCHEM, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(UNAUDITED)

(in thousands)

| | Three Months Ended October 31, | |
|--|--------------------------------------|-----------|
| | 2015 | 2014 |
| Net income (loss) | \$4,434 | \$(3,729) |
| Other comprehensive income (loss): | | |
| Foreign currency translation adjustments | 62 | 108 |
| Comprehensive income (loss) | \$4,496 | \$(3,621) |

The accompanying notes are an integral part of these consolidated financial statements.

ENZO BIOCHEM, INC.**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY****Three months ended October 31, 2015****(UNAUDITED)****(in thousands, except share data)**

| | Common Stock Shares | Common Stock Amount | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Income | Total Stockholders' Equity |
|---|---------------------------|---------------------------|----------------------------------|------------------------|---|----------------------------------|
| Balance at July 31, 2015 | 46,062,065 | \$ 461 | \$ 324,966 | \$ (284,682) | \$ 1,861 | \$ 42,606 |
| Net income for the period ended October 31, 2015 | — | — | — | 4,434 | — | 4,434 |
| Vesting of restricted stock | 6,751 | — | — | — | — | — |
| Share-based compensation charges | — | — | 111 | — | — | 111 |
| Foreign currency translation adjustments | — | — | — | — | 62 | 62 |
| Balance at October 31, 2015 | 46,068,816 | \$ 461 | \$ 325,077 | \$ (280,248) | \$ 1,923 | \$ 47,213 |

The accompanying notes are an integral part of these consolidated financial statements

ENZO BIOCHEM, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(in thousands)

| | Three Months Ended October 31, | |
|--|--------------------------------------|------------|
| | 2015 | 2014 |
| Cash flows from operating activities: | | |
| Net income (loss) | \$4,434 | \$(3,729) |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: | | |
| Depreciation and amortization of property, plant and equipment | 527 | 507 |
| Amortization of intangible assets | 423 | 431 |
| Provision for uncollectible accounts receivable | 704 | 541 |
| Deferred income tax benefit | (3) | (24) |
| Share-based compensation charges | 111 | 98 |
| Accrual for share-based 401(k) employer match expense | 166 | 145 |
| Foreign exchange loss | 129 | 422 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (1,376) | (482) |
| Other receivables – settlements | 6,650 | — |
| Inventories | (210) | 107 |
| Prepaid expenses and other | 442 | 182 |
| Accounts payable – trade | 682 | (1,157) |
| Accrued liabilities, other current liabilities and other liabilities | 474 | 204 |
| Total adjustments | 8,719 | 974 |
| Net cash provided by (used in) operating activities | 13,153 | (2,755) |
| Cash flows from investing activities: | | |
| Capital expenditures | (505) | (264) |
| Security deposits and other | 15 | 5 |
| Net cash used in investing activities | (490) | (259) |
| Cash flows from financing activities: | | |
| Net proceeds from issuance of common stock | — | 2,322 |
| Proceeds from borrowings under Credit Agreement | 22,461 | 22,360 |
| Repayments under Credit Agreement | (22,461) | (22,360) |
| Installment loan and capital lease obligation payments | (125) | (115) |
| Net cash (used in) provided by financing activities | (125) | 2,207 |
| Effect of exchange rate changes on cash and cash equivalents | (5) | (57) |
| Increase (decrease) in cash and cash equivalents | 12,533 | (864) |
| Cash and cash equivalents - beginning of period | 18,109 | 17,455 |
| Cash and cash equivalents - end of period | \$30,642 | \$16,591 |

The accompanying notes are an integral part of these consolidated financial statements.

7

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

As of October 31, 2015

(Unaudited)
(Dollars in thousands, except share data)

Note 1 – Basis of Presentation

The accompanying consolidated financial statements include the accounts of Enzo Biochem, Inc. and its wholly-owned subsidiaries, Enzo Life Sciences, Enzo Clinical Labs, Enzo Therapeutics and Enzo Realty LLC, collectively or with one or more of its subsidiaries referred to as the “Company” or “Companies”. The consolidated balance sheet as of October 31, 2015, the consolidated statements of operations, comprehensive income (loss), and cash flows for the three months ended October 31, 2015 and 2014, and the consolidated statement of stockholders’ equity for the three months ended October 31, 2015 are unaudited. In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present fairly the financial position and operating results for the interim periods have been made. Certain information and footnote disclosure, normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States, have been condensed or omitted. The consolidated financial statements should be read in conjunction with the consolidated financial statements for the year ended July 31, 2015 and notes thereto contained in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission. The consolidated balance sheet at July 31, 2015 has been derived from the audited financial statements at that date. The results of operations for the three months ended October 31, 2015 are not necessarily indicative of the results that may be expected for the fiscal year ending July 31, 2016.

Note 2 – Net income (loss) per share

Basic net income (loss) per share represents net income (loss) divided by the weighted average number of common shares outstanding during the period. As a result of the net loss for the three month period ended October 31, 2014, diluted weighted average shares outstanding are the same as basic weighted average shares outstanding, and do not include the potential common shares from stock options and unvested restricted stock because to do so would be antidilutive.

For the three months ended October 31, 2015, approximately 125,000 weighted average stock options were included in the calculation of diluted weighted average shares outstanding. For the three months ended October 31, 2014, the number of potential common shares (“in the money options”) and unvested restricted stock excluded from the

calculation of diluted earnings per share was 482,000.

For the three months ended October 31, 2015 and 2014, the effect of approximately 374,000 and 142,000 respectively, of outstanding “out of the money” options to purchase common shares were excluded from the calculation of diluted net income (loss) per share because their effect would be anti-dilutive.

Note 3 - Supplemental disclosure for statement of cash flows

For the three months ended October 31, 2015 and 2014, income taxes paid by the Company were \$27 and \$26, respectively.

For the three months ended October 31, 2015 and 2014, interest paid by the Company was \$41 and \$69, respectively.

For the three months ended October 31, 2015 and 2014, the Company financed \$38 and \$19 respectively, in machinery and transportation equipment under installment loans.

During the three months ended October 31, 2015, there was a total of \$157 in capital lease agreements. During the three months ended October 31, 2014, the Company did not enter into any capital lease agreements.

Note 4 - Inventories

Inventories consist of the following:

| | October 31, 2015 | July 31, 2015 |
|-------------------|------------------------|---------------------|
| Raw materials | \$ 1,109 | \$ 1,013 |
| Work in process | 1,984 | 2,002 |
| Finished products | 4,489 | 4,381 |
| | \$ 7,582 | \$ 7,396 |

Note 5 – Goodwill and intangible assets

At October 31, 2015 and July 31, 2015, the Company's net carrying amount of goodwill, related to the Clinical Labs segment, is \$7,452.

The Company's change in the net carrying amount of intangible assets, all of which is included in the Life Sciences segment is as follows:

| | Gross | Accumulated Amortization | Net |
|------------------------------|-----------|-----------------------------|----------|
| July 31, 2015 | \$ 27,838 | \$ (21,683) | \$ 6,155 |
| Amortization expense | — | (423) | (423) |
| Foreign currency translation | (97) | 72 | (25) |
| October 31, 2015 | \$ 27,741 | \$ (22,034) | \$ 5,707 |

Intangible assets consist of the following:

| | October 31, 2015 | | | July 31, 2015 | | |
|-------------------------------|------------------|-----------------------------|--------|---------------|-----------------------------|--------|
| | Gross | Accumulated Amortization | Net | Gross | Accumulated Amortization | Net |
| Patents | \$ 11,027 | \$ (10,879) | \$ 148 | \$ 11,028 | \$ (10,871) | \$ 157 |
| Customer relationships | 12,190 | (7,621) | 4,569 | 12,243 | (7,398) | 4,845 |
| Website and acquired content | 1,016 | (1,016) | — | 1,020 | (1,020) | — |
| Licensed technology and other | 515 | (443) | 72 | 518 | (441) | 77 |
| Trademarks | 2,993 | (2,075) | 918 | 3,029 | (1,953) | 1,076 |

Total \$27,741 \$ (22,034) \$5,707 \$27,838 \$ (21,683) \$6,155

At October 31, 2015, information with respect to intangibles assets acquired is as follows:

| | Useful life assigned | Weighted average remaining useful life |
|------------------------|---------------------------------|---|
| Customer relationships | 8-15 years | 5 years |
| Trademarks | 5 years | 2 years |
| Other intangibles | 10 years | 4 years |

At October 31, 2015, the weighted average useful life of amortizable intangible assets is approximately four years.

Note 6 - Loan Payable

On June 7, 2013, the Company entered into a secured Revolving Loan and Security Agreement (the "Credit Agreement") among the Company and certain of its subsidiaries, with Enzo Therapeutics as a guarantor, and Healthcare Finance Group, LLC (the "Lender"). The Credit Agreement, which expires in December 2016, provides for borrowings against eligible US receivables, as defined, of the Clinical Lab and Life Science segments up to \$8.0 million at defined eligibility percentages and provides for additional borrowings of \$4.0 million for increased eligible assets. Debt issuance costs of \$281 are being amortized over the life of the Credit Agreement. If the amount of

borrowings outstanding under the revolving credit facility exceeds the borrowing base then in effect, or the Lender requires a reserve, the Company will be required to repay such borrowings in an amount sufficient to eliminate such excess. Interest on advances, payable monthly, is based on the three month LIBOR rate, with a floor of 1.25% plus an applicable margin of 4.0%. In the event of any default, the interest rate may be increased 3.0% over the current rate. The facility also carries a non-utilization fee of 0.50% per annum, payable monthly, on the unused portion of the Credit Agreement. At October 31, 2015 and July 31, 2015, the borrowings under the Credit Agreement related to the Clinical Labs and Life Sciences receivables aggregated \$3.0 million.

The Company's obligations under the Credit Agreement are secured by primarily all the unencumbered U.S. assets of the Company, excluding buildings and intellectual property which the Lender has a negative pledge, and the capital stock of subsidiaries. The Credit Agreement includes customary affirmative and negative covenants and events of default and requires maximum levels of cash usage and minimum levels of liquidity, as defined, and provides for increased liquidity levels if operating results are not achieved. Negative covenants include among others, limitations on additional debt, liens, loans or investments, distributions, asset sales and affiliate transactions. Events of default include non-payment of principal and interest on debt outstanding, non-performance of covenants, material change in business, breach of representations, bankruptcy and insolvency, material judgments and changes in control. In July 31, 2013, the lender modified various financial covenants relating to fiscal 2014. As of October 31, 2015, the Company is in compliance with the financial covenants.

The Credit Agreement includes customary affirmative and negative covenants and events of default. The terms of the debt covenants include:

○ The minimum balance the Company must borrow at any time is \$2.0 million. At October 31 2015, the loan balance was approximately \$3.0 million, with an additional availability of \$2.4 million.

○ The Company must maintain a Minimum Liquidity, as defined in the Credit Agreement, of not less than \$3.0 million. At October 31, 2015, the Company's Minimum Liquidity was \$11.0 million.

○ The quarterly Cash Burn, as defined in the Credit Agreement, must be greater than zero. During the three months ended October 31, 2015, the Cash Burn was positive in the amount of \$1.4 million.

As of October 31, 2015, the Credit Agreement was amended to redefine Cash Burn and add a definition for Liquidity (the "amendment"). Under the amendment, the determination of Cash Burn during a fiscal quarter excludes capital expenditures provided that Liquidity exceeds \$7 million as of the last day of the fiscal quarter. As of October 31, 2015, Liquidity as defined was \$33.1 million.

Based on its current level of Minimum Liquidity and Cash Burn, the Company believes it will continue to be in compliance with the financial covenants in future periods; however there are no assurances of such compliance. Based on our ability to comply with financial covenants in the past, our ability to obtain covenant waivers previously, and our expected future performance, we believe we would be able to cure a non-compliance event and obtain a Lender

waiver. The Company currently believes that the Lender would be willing to negotiate and provide waivers to the Company in the event of non-compliance with covenants, although there can be no assurances. In addition, the Company believes the effects of non-compliance with the covenants would not have a material effect on our financial condition and liquidity due to cash provided by operating cash flows and funds available under the Company's Controlled Equity Offering program.

Note 7 – Accrued Liabilities and Other Current Liabilities

Accrued liabilities consist of the following:

| | October 31, 2015 | July 31, 2015 |
|------------------------------------|------------------------|------------------|
| Legal fee expense | \$4,999 | \$4,183 |
| Payroll, benefits, and commissions | 4,717 | 3,907 |
| Professional fees | 491 | 678 |
| Research and development | 300 | 300 |
| Other | 1,850 | 2,229 |
| | \$12,357 | \$11,297 |

Note 8 – Other Liabilities

Other liabilities consist of the following:

| | October 31, 2015 | July 31, 2015 |
|--|------------------------|---------------------|
| Accrued legal settlement | \$ 807 | \$ 1,220 |
| Capital lease obligations, net of short term | 305 | 210 |
| Installment loans, net of short term | 245 | 363 |
| | \$ 1,357 | \$ 1,793 |

As of October 31, 2015, future minimum payments under the capital leases, net of interest of \$23 aggregates \$579, including a short term debt portion of \$274 included in other current liabilities. Future minimum payments under the installment loans aggregate \$534, including a short term portion of \$289 included in other current liabilities. A total of \$1.2 million was recorded in other current liabilities and in other liabilities as accrued legal settlement which is further discussed in Note 13 - Contingencies.

Note 9 – Stockholders' Equity***Controlled Equity Offering***

On March 28, 2013, the Company entered into a Controlled Equity OfferingSM Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor"). Under the Sales Agreement, the Company may offer and sell, from time to time, through Cantor, shares of the Company's common stock, par value \$0.01 per share (the "Common Stock"), having an aggregate offering price of up to \$20.0 million (the "Shares"). The Company will pay Cantor a commission of 3.0% of the aggregate gross proceeds received under the Sales Agreement. The Company is not obligated to make any sales of the Shares under the Sales Agreement. The offering of Shares pursuant to the Sales Agreement will terminate upon the earlier of (a) the sale of all of the Shares subject to the Sales Agreement or (b) the termination of the Sales Agreement by Cantor or the Company, as permitted therein. The Shares were initially issued pursuant to the Company's Registration Statement on Form S-3 which was declared effective on August 5, 2010 and a prospectus supplement, dated March 28, 2013, and more recently under the Company's current Registration Statement on Form S-3 which was declared effective on August 13, 2013 and a prospectus supplement dated August 1, 2013, filed by the Company with the Securities and Exchange Commission (the "SEC").

On December 31, 2014, the Sales Agreement was amended in order for the Company to offer and sell, through Cantor, acting as agent, additional shares of Common Stock having an aggregate offering price of \$20.0 million. In connection with the amendment to the Sales Agreement, the Company also filed with the SEC a prospectus

supplement dated December 31, 2014.

During the three months ended October 31, 2015, the Company did not sell any shares of Common Stock under the Sales Agreement. For the three months ended October 31, 2014, the Company sold an aggregate of 505,829 shares of Common Stock under the Sales Agreement at an average price of \$5.38 per share and received proceeds of approximately \$2.6 million, net of expenses of \$82.

Share-based compensation

The Company has an incentive stock option and restricted stock award plan (the “2005 Plan”), and a long term incentive share award plan, (the “2011 Incentive Plan”), which are more fully described in Note 10 to the consolidated financial statements included in the Company’s Annual Report on Form 10-K for the fiscal year ended July 31, 2015. The 2011 Plan, which is the only plan from which awards may now be granted, provides for the award to eligible employees, officers, directors, consultants and other persons of stock options, stock appreciation rights (SARs), restricted stock, restricted stock units, performance awards, and other stock-based awards.

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

The amounts of share-based compensation expense recognized in the periods presented are as follows:

| | Three months ended October 31, 2015 2014 | |
|------------------|--|-------|
| Stock options | \$104 | \$ 85 |
| Restricted stock | 7 | 13 |
| | \$111 | \$ 98 |

The following table sets forth the amount of expense related to share-based payment arrangements included in specific line items in the accompanying statements of operations:

| | Three months ended October 31, 2015 2014 | |
|--------------------------------------|--|-------|
| Cost of clinical laboratory services | \$1 | \$ 1 |
| Research and development | — | 1 |
| Selling, general and administrative | 110 | 96 |
| | \$111 | \$ 98 |

No excess tax benefits were recognized during the three month periods ended October 31, 2015 and 2014.

Stock Option Plans

The following table summarizes stock option activity during the three month period ended October 31, 2015:

| | Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value (000s) |
|------------------------------|-----------|--|---|---|
| Outstanding at July 31, 2015 | 1,358,104 | \$ 3.04 | | |
| Awarded | — | \$ — | | |
| Exercised | — | \$ — | | |
| Cancelled or expired | (6,000) | \$ 3.61 | | |

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

| | | | | |
|------------------------------|-----------|---------|-----------|--------|
| Outstanding at end of period | 1,352,104 | \$ 3.04 | 2.2 years | \$ 964 |
| Exercisable at end of period | 785,188 | \$ 2.87 | 1.8 years | \$ 664 |

As of October 31, 2015, the total future compensation cost related to non-vested options, not yet recognized in the statements of operations, was \$0.4 million and the weighted average period over which the remaining expense of these awards is expected to be recognized is eleven months.

The intrinsic value of in the money stock option awards that are vested at the end of the period represents the Company's closing stock price on the last trading day of the period in excess of the exercise price multiplied by the number of options that vested.

Restricted Stock Awards

A summary of the activity pursuant to the Company's unvested restricted stock awards for the three months ended October 31, 2015 is as follows:

| | Awards | Weighted Average Award Price |
|------------------------------|----------|---------------------------------------|
| Outstanding at July 31, 2015 | 21,501 | \$ 8.84 |
| Awarded | — | \$ — |
| Vested | (6,751) | \$ (2.10) |
| Forfeited | (1,500) | \$ (2.86) |
| Unvested at end of period | 13,250 | \$ 4.04 |

12

The fair value of a restricted stock award is determined based on the closing stock price on the award date. As of October 31, 2015, there was approximately \$0.1 million of unrecognized compensation cost related to unvested restricted stock-based compensation to be recognized over a weighted average remaining period of approximately twenty-one months. The fair value of the awards that vested during the three months ended October 31, 2015 and 2014 was \$21 and \$35, respectively.

The total number of shares available for grant as equity awards from the 2011 Incentive Plan is approximately 1,309,000 shares as of October 31, 2015.

Note 10 - Income taxes

At the end of each interim reporting period, the Company estimates its effective income tax rate expected to be applicable for the full year. This estimate is used to determine the income tax provision or benefit on a year-to-date basis and may change in subsequent interim periods.

The Company's effective tax rate provision for the three months ended October 31, 2015 was 1.9% compared to 3.4% for the three months ended October 31, 2014. The tax provision for the periods was based on state, local and foreign taxes, net of the benefit for amortization of foreign intangibles. The Company's effective tax rate for both periods differed from the expected net operating loss carryforward benefit at the U.S. federal statutory rate of 34% primarily due to the inability to recognize such benefit. The carryforward benefit cannot be recognized because of uncertainties relating to future taxable income in terms of both its timing and its sufficiency, which would enable the Company to realize the federal carryforward benefit.

The Company files a consolidated Federal income tax return. The Company files combined returns with California, Michigan and New York State and City for certain subsidiaries. Other subsidiaries file separate state and foreign tax returns.

Note 11 – Royalty and licensing income

The Company's Life Science segment has a license agreement with Qiagen that began in 2005, whereby the Company earns quarterly royalties on the net sales of Qiagen products subject to the license until the expiration of the patent on April 24, 2018. During the three months ended October 31, 2015 and 2014, the Company recorded royalty income under the agreement of approximately \$0.4 million and \$1.0 million respectively, which is included in the Life Sciences segment.

Note 12 – Segment reporting

The Company has three reportable segments: Clinical Labs, Life Sciences, and Therapeutics. The Clinical Labs segment provides diagnostic services to the health care community. The Company's Life Sciences segment develops, manufactures, and markets products to research and pharmaceutical customers. The Company's Therapeutic segment conducts research and development activities for therapeutic drug candidates. The Company evaluates segment performance based on segment income (loss) before taxes. Costs excluded from segment income (loss) before taxes and reported as "Other" consist of corporate general and administrative costs which are not allocable to the three reportable segments.

Legal fee expense incurred to defend the Company's intellectual property and other general corporate matters is considered a component of the Other segment. Legal fee expense specific to other segments' activities has been allocated to those segments. Legal settlements, net represent activities for which royalties would have been received by the Company's Life Sciences segment had the Company had agreements in place with plaintiffs for the products covered by the settlements.

Management of the Company assesses assets on a consolidated basis only and, therefore, assets by reportable segment have not been included in the reportable segments below. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies contained in the Company's Annual Report on Form 10-K for the year ended July 31, 2015.

The following financial information represents the operating results of the reportable segments of the Company:

Three months ended October 31, 2015

| | Clinical Labs | Life Sciences | Therapeutics | Other | Consolidated |
|---|--------------------------|--------------------------|---------------------|--------------|---------------------|
| Revenues: | | | | | |
| Clinical laboratory services | \$17,090 | — | — | — | \$ 17,090 |
| Product revenues | — | \$ 7,687 | — | — | 7,687 |
| Royalty and license fee income | — | 400 | — | — | 400 |
| | 17,090 | 8,087 | — | — | 25,177 |
| Operating expenses: | | | | | |
| Cost of clinical laboratory services | 10,332 | — | — | — | 10,332 |
| Cost of product revenues | — | 3,611 | — | — | 3,611 |
| Research and development | — | 667 | \$ 200 | — | 867 |
| Selling, general and administrative | 5,286 | 3,059 | — | \$1,880 | 10,225 |
| Provision for uncollectible accounts receivable | 708 | (4) | — | — | 704 |
| Legal fee expense | 9 | (22) | — | 1,614 | 1,601 |
| Legal settlement, net | — | (6,800) | — | — | (6,800) |
| Total operating expenses | 16,335 | 511 | 200 | 3,494 | 20,540 |
| Operating income (loss) | 755 | 7,576 | (200) | (3,494) | 4,637 |
| Other income (expense) | | | | | |
| Interest | (19) | 14 | — | (35) | (40) |
| Other | 4 | 39 | — | 11 | 54 |
| Foreign exchange loss | — | (130) | — | — | (130) |
| Income (loss) before income taxes | \$740 | \$ 7,499 | \$ (200) | \$ (3,518) | \$ 4,521 |
| Depreciation and amortization included above | \$397 | \$ 530 | \$ — | \$23 | \$ 950 |
| Share-based compensation included in above: | | | | | |
| Cost of clinical laboratory services | \$1 | — | — | — | \$ 1 |
| Research and development | — | \$— | — | — | — |
| Selling, general and administrative | 10 | 5 | — | \$95 | 110 |
| Total | \$11 | \$ 5 | — | \$95 | \$ 111 |
| Capital expenditures | \$437 | \$ 68 | \$ — | \$— | \$ 505 |

Three months ended October 31, 2014

| | Clinical Labs | Life Sciences | Therapeutics | Other | Consolidated |
|---|------------------|------------------|--------------|------------|--------------|
| Revenues: | | | | | |
| Clinical laboratory services | \$15,822 | — | — | — | \$ 15,822 |
| Product revenues | — | \$ 8,002 | — | — | 8,002 |
| Royalty and license fee income | — | 1,000 | — | — | 1,000 |
| | 15,822 | 9,002 | — | — | 24,824 |
| Operating expenses: | | | | | |
| Cost of clinical laboratory services | 10,130 | — | — | — | 10,130 |
| Cost of product revenues | — | 3,695 | — | — | 3,695 |
| Research and development | — | 548 | \$ 243 | — | 791 |
| Selling, general and administrative | 5,066 | 3,150 | — | \$2,069 | 10,285 |
| Provision for uncollectible accounts receivable | 530 | 11 | — | — | 541 |
| Legal fee expense | 91 | 1 | — | 2,374 | 2,466 |
| Total operating expenses | 15,817 | 7,405 | 243 | 4,443 | 27,908 |
| Operating income (loss) | 5 | 1,597 | (243) | (4,443) | (3,084) |
| Other income (expense) | | | | | |
| Interest | (27) | 2 | — | (44) | (69) |
| Other | 2 | (8) | — | 25 | 19 |
| Foreign exchange gain | — | (472) | — | — | (472) |
| Income (loss) before income taxes | \$(20) | \$ 1,119 | \$ (243) | \$(4,462) | \$(3,606) |
| Depreciation and amortization included above | \$357 | \$ 560 | \$ 1 | \$20 | \$ 938 |
| Share-based compensation included in above: | | | | | |
| Cost of clinical laboratory services | \$1 | — | — | — | \$ 1 |
| Research and development | — | 1 | — | — | 1 |
| Selling, general and administrative | 9 | \$— | — | \$87 | 96 |
| Total | \$10 | \$ 1 | — | \$87 | \$ 98 |
| Capital expenditures | \$254 | \$ 10 | \$ — | \$— | \$ 264 |

Note 13 – Contingencies

On June 7, 2004, the Company and Enzo Life Sciences, Inc., filed suit in the United States District Court for the District of Connecticut against Applera Corporation and its wholly-owned subsidiary Tropix, Inc., which became Life Technologies, Inc. (NASDAQ:LIFE) and was acquired by Thermo Fisher Scientific, Inc. (NYSE:TMO) on February 3, 2014. The complaint alleged infringement of six patents relating to DNA sequencing systems, labeled nucleotide products, and other technology. Yale University is the owner of four of the patents and the Company is the exclusive licensee. These four patents are commonly referred to as the “Ward” patents. On November 12, 2012, a jury in New Haven found that one of these patents (United States Patent No. 5,449,667) was infringed and not proven invalid. The jury awarded \$48.5 million for this infringement. On January 6, 2014, the judge awarded prejudgment interest of approximately \$12.5 million and additional post-interest on the full amount will also be awarded starting November 7, 2012 until the total award is satisfied. The final award to the Company could be reduced or be subject to possible claims from third parties. On March 16, 2015, the Court of Appeals for the Federal Circuit vacated that judgment in a decision remanding the matter to the district court for further proceedings. The Company has moved for reconsideration of that decision by the panel and for en banc rehearing by the full Court. There can be no assurance that the Company will be successful in this litigation. Even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact on the Company.

As of August 1, 2014 the Company was engaged in litigation in the United States District Court for the Southern District of New York against Roche Diagnostic GmbH and its related company Roche Molecular Systems, Inc. (“Roche”), as declaratory judgment defendant. This case was commenced in May 2004. Roche seeks a declaratory judgment of non-breach of contract and patent invalidity against the Company. Roche has also asserted tort claims against the Company. The Company has asserted breach of contract and patent infringement causes of action against Roche. There has been extensive discovery in the case. In 2011, Roche moved for summary judgment of non-infringement regarding the Company’s patent claims. In 2012, the motion was granted in part and denied in part. In December 2012, Roche moved for summary judgment on the Company’s non-patent claims. Additional discovery was taken and the Company responded to the motions in May 2013. On December 6, 2013, the Court granted in part and denied in part Roche’s summary judgment motion. On October 22, 2014, the Court ordered that damages discovery concerning the Company’s remaining contract and patent claims and Roche’s claims should be completed by January 30, 2015, and expert discovery should be completed following the Court’s not-yet-issued claim construction ruling concerning the Company’s patent infringement claim against Roche. Roche dropped its tort claims during damages discovery. On April 28, 2015, the Court heard oral argument on claim construction issues. On May 8, 2015, Roche and the Company jointly moved the Court to extend the schedule for damages discovery until May 29, 2015, and the Court granted that motion. The litigation in the United States District Court for the Southern District of New York between the Company and Molecular Probes, Inc. terminated on May 11, 2015, with a settlement in favor of the Company in the amount of \$170. Through October 31, 2015, the Company’s former legal counsel, Greenberg Traurig LLP (“GT”), was also engaged in litigation against the Company in the United States District Court for the Southern District of New York concerning GT’s request for a charging lien against another matter relating to its representation of the Company in the Roche and other cases.

On April 22, 2014, the Company as plaintiff finalized and executed a settlement agreement with Affymetrix, Inc. to settle patent litigation actions before the U.S. District Court, Southern District of New York (the “Agreement”) in the amount of \$5.1 million. Under terms of the Agreement, Affymetrix paid to the Company \$4.3 million and paid to the Company’s attorneys \$0.8 million.

On June 20, 2014, the Company, as plaintiff finalized and executed a settlement agreement with PerkinElmer, Inc., and PerkinElmer Health Sciences, Inc. (formerly known as PerkinElmer Life Sciences, Inc.) (together, "PerkinElmer"), with respect to an action between the Company and PerkinElmer before the U.S. District Court, Southern District of New York, Case No 03-CV-3817. PerkinElmer paid \$7.0 million in escrow pursuant to the agreement because of GT's requesting a charging lien for fees allegedly owed for past services rendered to the Company as referenced above. Because the settlement proceeds were held in escrow, and the amount the Company would ultimately receive was indeterminable, the Company has not included the settlement in the financial statements as of or for any periods through October 31, 2015. Any applicable amounts will be recognized when so distributed. On December 3, 2015, the Company entered into a Settlement Agreement with GT pursuant to which the Company and GT resolved their respective claims against each other. The escrow referred to above will be distributed in accordance with the terms of the Settlement Agreement, upon the entry by the Court of the Stipulation, Order and Judgement.

In 2012, the Company received a Subpoena Duces Tecum (the “Subpoena”) from the Department of Health and Human Services, Office of Inspector General (“OIG”). The Subpoena was issued as part of an investigation being conducted by the US Attorney’s Office for the Eastern District of New York in conjunction with the OIG. While a number of potential issues were raised initially by the government, the investigation came to focus primarily on an alleged failure to collect diagnosis codes from physicians who ordered tests through Enzo Clinical Labs. The time period initially covered by the investigation was from 2004 through 2011. In response to the Subpoena, the Company cooperated with the government. On September 22, 2014, the Company and the U.S. Department of Justice reached a settlement agreement to resolve this matter, in substantive form as disclosed in the Company’s fiscal quarter ended April 30, 2014. During the quarter ended April, 30, 2014, the Company recorded a charge of \$2.0 million in the statement of operations under legal settlements, net within the Clinical Labs segment. The settlement amount will be paid with interest over a five-year period. As of October 31, 2015, the Company carried a balance of \$0.4 million as other current liabilities and \$0.8 million as a non-current liability. Under certain circumstances, the Company may be required to accelerate payments and/or pay up to an additional \$1.5 million based upon (i) a favorable recovery and collection related to the judgment in the Life Technologies matter discussed above, (ii) receipt of additional capital greater than \$10.0 million in a fiscal year (in that case, the Company is required to pay 20% of any amount over \$10.0 million plus interest, or (iii) sale of the Company. The final settlement covers the time period 2004-2014.

On July 2, 2015, the Company as Plaintiff executed a settlement agreement with Luminex Corporation with respect to an action between the Company and Abbott Laboratories and Abbott Molecular, Inc (Defendants) and Luminex Corporation (Intervening Defendant) before the United States District Court for the District of Delaware for alleged patent infringement. Luminex paid the Company a total of \$7.1 million as consideration for this agreement and the dismissal of the litigation against Luminex.

On July 20, 2015, the Company as a Plaintiff finalized and executed a settlement agreement with Siemens Healthcare Diagnostics Inc. (“Siemens”) to settle a patent litigation lawsuit before the U.S. District Court for the District of Delaware in the amount of \$9.5 million. Under terms of the agreement, Siemens will also pay the Company additional royalties of \$1.0 million per annum on sales of its molecular products manufactured and/or sold in the United States during the its fiscal years 2015 through 2019 if sales of such products exceed a contractual amount. The net settlement amount was included in other receivables in the consolidated balance sheet as of July 31, 2015 and was received in August 2015.

On October 9, 2015, the Company reached and finalized a settlement with Affymetrix, Inc. in the amount of \$6.8 million, net in an infringement action brought by the Company regarding its US Patent no. 7,064,197. The case was originally brought by the Company in the United States District Court for the District of Delaware. This settlement is included in statement of operations under Legal settlements, net within the Life Science segment.

The Company is party to other claims, legal actions, complaints, and contractual disputes that arise in the ordinary course of business. The Company believes that any liability that may ultimately result from the resolution of these matters will not, individually or in the aggregate, have a material adverse effect on its financial position or results of operations

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes and other information included elsewhere in this Quarterly Report on Form 10-Q.

Forward-Looking Statements

Our disclosure and analysis in this report, including but not limited to the information discussed in this Item 2, contain forward-looking information about our Company's financial results and estimates, business prospects and products in research and development that involve substantial risks and uncertainties. From time to time, we also may provide oral or written forward-looking statements in other materials we release to the public. Forward-looking statements give our current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historic or current facts. They use words such as "anticipate", "estimate", "expect", "project", "intend", "plan", "believe", "will", and other words and terms of similar meaning in connection with any discussion of future operations or financial performance. In particular, these include statements relating to future actions, prospective products or product approvals, future performance or results of current and anticipated products, sales efforts, expenses, interest rates, foreign currency rates, intellectual property matters, the outcome of contingencies, such as legal proceedings, and financial results.

We cannot guarantee that any forward-looking statement will be realized, although we believe we have been prudent in our plans and assumptions. Achievement of future results is subject to risks, uncertainties and inaccurate assumptions. Should known or unknown risks or uncertainties materialize, or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected. As a result, investors are cautioned not to place undue reliance on any of our forward-looking statements. Investors should bear this in mind as they consider forward-looking statements. We do not assume any obligation to update or revise any forward-looking statement that we make, even if new information becomes available or other events occur in the future. We are also affected by other factors that may be identified from time to time in our filings with the Securities and Exchange Commission, some of which are set forth in Item 1A - Risk Factors in our Form 10-K filing for the July 31, 2015 fiscal year. You are advised to consult any further disclosures we make on related subjects in our Forms 10-Q, 8-K and 10-K reports to the Securities and Exchange Commission. Although we have attempted to provide a list of important factors which may affect our business, investors are cautioned that other factors may prove to be important in the future and could affect our operating results. You should understand that it is not possible to predict or identify all such factors or to assess the impact of each factor or combination of factors on our business. Consequently, you should not consider any such list to be a complete set of all potential risks or uncertainties.

Overview

Enzo Biochem, Inc. (the “Company” “we”, “our” or “Enzo”) is a growth-oriented biotechnology company focusing on delivering and applying advanced technology capabilities to produce affordable reliable products and services to allow our customers to meet their clinical needs. We develop, manufacture and sell our proprietary technology solutions and platforms to clinical laboratories, specialty clinics and researchers and physicians globally. Our pioneering work in genomic analysis coupled with our extensive patent estate and enabling platforms have positioned the Company to continue to play an important role in the rapidly growing molecular medicine marketplaces.

Enzo technology solutions and platforms and unique operational structure is designed to reduce overall healthcare costs to both government and private insurers. Our proprietary technology platforms reduces our customers’ need for multiple, specialized instruments, and offer a variety of throughput capabilities together with a demonstrated high level of accuracy and reproducibility. Our genetic test panels are focused on large and growing markets primarily in the areas of personalized medicine, women’s health, infectious diseases and genetic disorders.

For example, our Ampiprobe™ technology platform can lead to the development of an entire line of nucleic acid clinical products that can allow laboratories to offer a complete menu of services at a cost that allows them to enjoy an acceptable margin. In November 2015, New York State approved our first assay based on the Ampiprobe platform aimed at providing affordable molecular diagnostics in light of reimbursement pressure. Our technology solutions provide tools to physicians, clinicians and other health care providers to improve detection, treatment and monitoring of a broad spectrum of diseases and conditions. In addition, reduced patient to physician office visits translates into lower healthcare processing costs and greater patient services.

We are comprised of three operating segments that have evolved out of our core competence: the use of nucleic acids as informational molecules and the use of compounds for immune modulation.. Information concerning sales by

geographic area and business segments for fiscal year ended July 31, 2015 can be found in our Form 10-K Note 15 in the Notes to Consolidated Financial Statements.

Below are brief descriptions of each of our operating segments (See Note 12 in the Notes to Consolidated Financial Statements):

Enzo Clinical Labs is a clinical reference laboratory providing a wide range of clinical services to a physicians, medical centers, other clinical labs and pharmaceutical companies. The Company believes having a College of American Pathologists (“CAP”) certified medical laboratory located in New York provides us to the opportunity to more rapidly introduce cutting edge products and services to the clinical marketplace. Enzo Clinical Labs offers an extensive menu of molecular and other clinical laboratory tests or procedures used in patient care by physicians to establish or support a diagnosis, monitor treatment or medication, and search for an otherwise undiagnosed condition. Our laboratory is equipped with state of the art communication and connectivity solutions enabling the rapid transmission, analysis and interpretation of generated data. We operate a full service clinical laboratory in Farmingdale, New York, a network of over 30 patient service centers throughout New York and New Jersey, a free standing “STAT” or rapid response laboratory in New York City and a full service phlebotomy, in-house logistics department, and information technology department.

Enzo Life Sciences manufactures, develops and markets products and tools to clinical research, drug development and bioscience research customers worldwide. Underpinned by broad technological capabilities, Enzo Life Sciences has developed proprietary products used in the identification of genomic information by laboratories around the world.

Information regarding our technologies can be found in the “Core Technologies” section. We are internationally recognized and acknowledged as a leader in the development, manufacturing validation and commercialization of numerous products serving not only the clinical research market but life sciences researchers in the fields of cellular analysis and drug discovery, among others. Our operations are supported by global operations allowing for the efficient marketing and delivery of our products around the world.

Enzo Therapeutics is a biopharmaceutical venture that has developed multiple novel approaches in the areas of gastrointestinal, infectious, ophthalmic and metabolic diseases, many of which are derived from the pioneering work of Enzo Life Sciences. Enzo Therapeutics has focused its efforts on developing treatment regimens for diseases and conditions for which current treatment options are ineffective, costly, and/or cause unwanted side effects. This focus has generated a clinical and preclinical pipeline, as well as more than 111 patents and patent applications.

Results of Operations

Three months ended October 31, 2015 compared to October 31, 2014

(in 000s)

Comparative Financial Data for the Three Months Ended October 31,

| Revenues: | 2015 | 2014 | Increase (Decrease) | % Change | |
|---|----------|----------|------------------------|-------------|---|
| Clinical laboratory services | \$17,090 | \$15,822 | \$ 1,268 | 8 | % |
| Product revenues | 7,687 | 8,002 | (315) | (4) |) |
| Royalty and license fee income | 400 | 1,000 | (600) | (60) |) |
| Total revenues | 25,177 | 24,824 | 353 | 1 |) |
| Operating expenses: | | | | | |
| Cost of clinical laboratory services | 10,332 | 10,130 | 202 | 2 | |
| Cost of product revenues | 3,611 | 3,695 | (84) | (2) |) |
| Research and development | 867 | 791 | 76 | 10 | |
| Selling, general, and administrative | 10,225 | 10,285 | (60) | (1) |) |
| Provision for uncollectible accounts receivable | 704 | 541 | 163 | 30 | |
| Legal fee expense | 1,601 | 2,466 | (865) | (35) |) |
| Legal settlements, net | (6,800) | — | (6,800) | ** |) |
| Total operating expenses | 20,540 | 27,908 | (7,368) | (26) |) |
| Operating income (loss) | 4,637 | (3,084) | (7,721) | ** |) |
| Other income (expense): | | | | | |
| Interest | (40) | (69) | (29) | (42) |) |
| Other | 54 | 19 | (35) | ** |) |
| Foreign exchange loss | (130) | (472) | (342) | (72) |) |

| | | | | | |
|-----------------------------------|---------|-----------|-----------|---|----|
| Income (loss) before income taxes | \$4,521 | \$(3,606) | \$(8,127) |) | ** |
|-----------------------------------|---------|-----------|-----------|---|----|

**** not meaningful**

Consolidated Results:

The “2016 period” and the “2015 period” refer to the three months ended October 31, 2015 and 2014, respectively.

Clinical laboratory services revenues for the 2016 period were \$17.1 million compared to \$15.8 million, an increase of \$1.3 million or 8%. The increase in revenue from fiscal year 2015 to 2016 is mainly attributed to an increase in molecular testing volume and new account acquisitions.

Product revenues for the 2016 period were \$7.7 million compared to \$8.0 million in the 2015 period, a decrease of \$0.3 million or 4%. The decrease was due to the negative impact of translating revenues denominated in the euro, pound sterling and Swiss franc which depreciated versus the US dollar in the 2016 period compared to the 2015 period (\$0.2 million) and declines in sales of non-proprietary products (\$0.1 million), primarily in markets other than the United States.

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

Royalty and license fee income during the 2016 period was \$0.4 million compared to \$1.0 million in the 2015 period a decrease of \$0.6 million or 60%. Royalties are primarily earned from the reported sales of Qiagen products subject to a license agreement. Qiagen has experienced declines in its US sales of HPV products which in turn reduces our royalty income. There are no direct expenses relating to royalty and licensing income.

The cost of clinical laboratory services during the 2016 period was \$10.3 million as compared to \$10.1 million in the 2015 period, an increase of \$0.2 million or 2%.

The cost of product revenues during the 2016 period was \$3.6 million compared to \$3.7 million in the 2015 period, a decrease of \$0.1 million or 2%. The gross profit margin was 53% in the 2016 period versus 54% in the 2015 period.

Research and development expenses were approximately \$0.9 million during the 2016 period, compared to \$0.8 million in the 2015 period, an increase of \$0.1 million or 10%. The increase was attributed to payroll and material costs related to new product development.

Selling, general and administrative expenses were approximately \$10.2 million during the 2016 period versus \$10.3 during the 2015 period. The Clinical Lab segment selling, general and administrative increased \$0.2 million primarily due to increases in selling costs and related expenses. Other segment selling, general and administrative decreased \$0.2 million due to lower compensation related costs.

The provision for uncollectible accounts receivable, primarily related to the Clinical Labs segment, was \$0.7 million for the 2016 period as compared to \$0.5 million in the 2015 period, an increase of \$0.2 million or 30%. The increase is primarily due to the increase in self-pay patient revenues. As a percent of Clinical laboratory services, the provision for uncollectible accounts receivable in the 2016 and 2015 periods was 4.1% and 3.4%, respectively.

Legal fee expense was \$1.6 million during the 2016 period compared to \$2.5 million in the 2015 period, a decrease of \$0.9 million or 35% primarily due to the timing of legal fees and related costs associated with ongoing patent litigation.

Legal settlements, net was \$(6.8) million in the 2016 period. During the 2016 period the Company as plaintiff finalized and executed a settlement agreement with Affymetrix, Inc.

Interest expense was \$0.1 million during the 2016 and 2015 periods due to interest incurred and fees relating to the credit agreement entered into in 2013.

During the 2016 and the 2015 periods, the foreign currency loss was \$0.1 million and \$0.5 million, respectively, a favorable change of \$0.3 million. The Company has loans and receivables with its foreign subsidiaries which may be denominated in US dollars or a foreign currency. When re-measuring these amounts into the respective entities' functional currency, the Company recognizes a loss if those foreign currencies, including the Swiss Franc, British pound and Euro depreciate relative to the US dollar during the period and a gain if those foreign currencies appreciate relative to the US dollar. During the 2016 period, the Swiss franc and British pound depreciated approximately 2% versus the US dollar and the Euro appreciated by less than a half percent. During the 2015 period, all three currencies experienced greater depreciation, of between 5.1% and 5.9% relative to the US dollar.

Segment Results:

Clinical Labs

The Clinical Labs segment's income before taxes was \$0.7 million for 2016 period as compared to a loss of \$(0.02) million in the 2015 period, an improvement year over year of \$0.7 million. Revenue from laboratory services for the 2016 period were \$17.1 million compared to \$15.8 in the 2015 period. The increase of \$1.3 million is mainly attributed to an increase in molecular testing volume and new account acquisitions. Cost of sales during the 2016 period was \$10.3 million as compared to \$10.1 million in the 2015 period, an increase of \$0.2 million. Clinical Lab gross profit margin was 40% in the 2016 period and 36% in the 2015 period. The provision for uncollectable accounts was \$0.7 million as compared to \$0.5 million; the increase is primarily due to higher self-pay patient revenues.

Life Sciences

The Life Sciences segment's income before taxes was \$7.5 million for the 2016 period as compared to \$1.1 million for the 2015 period, an improvement of \$6.4 million over fiscal 2015. The 2016 period includes \$6.8 million for a

patent litigation settlement agreement previously described. Product revenues decreased \$0.3 million or 4% in the 2016 period due to the negative impact of translating revenues denominated in foreign currencies into the US dollar (\$0.2 million) and by declines in sales of non-proprietary products (\$0.1 million), primarily in markets other than the United States. The segment's gross profit was \$4.5 million in the 2016 period, as compared \$5.3 million in the 2015 period, a decrease of \$0.8 million primarily due to a decrease in royalty and license fee income of \$0.6 million and a gross margin decrease of \$0.2 million on lower product revenues. The segment's other operating expenses, excluding legal and legal settlements, net, in the 2016 period was unchanged compared to 2015. Due to smaller depreciation of foreign currencies versus the US dollar, including the Swiss Franc, British pound and Euro during the 2016 period, the foreign currency loss was \$0.1 million compared to a \$0.4 million in the 2015 period, resulting in a favorable change of \$0.3 million in the 2016 period.

Therapeutics

Therapeutics loss before income taxes was approximately \$0.2 million in the 2016 and 2015 periods.

Other

The Other loss before taxes for the 2016 period was approximately \$3.5 million as compared to \$4.5 million for the 2015 period, a decrease of \$1.0 million due to lower legal fee expense and related costs associated with ongoing patent litigation of \$0.8 million and a decrease of \$0.2 million in compensation related costs.

Liquidity and Capital Resources

At October 31, 2015, the Company had cash and cash equivalents of \$30.6 million of which \$0.4 million was in foreign accounts, as compared to cash and cash equivalents of \$18.1 million, of which \$0.5 million was in foreign accounts at July 31, 2015. It is the Company's current intent to permanently reinvest these funds outside of the United States, and its current plans do not demonstrate a need to repatriate them to fund its United States operations. The Company had working capital of \$27.0 million at October 31, 2015 compared to \$22.5 million at July 31, 2015. The increase in working capital of \$4.5 million was primarily due to the recognition of \$6.8 million in income from Legal settlements, net from a patent litigation settlement agreement, offset by net changes in operating assets and liabilities.

Net cash provided by operating activities as of October 31, 2015 was approximately \$13.2 million as compared to cash used in operating activities of \$2.8 million in fiscal 2014, an increase of approximately \$16.0 million. The increase in the 2016 period was primarily due to a net change in operating assets and liabilities of \$7.8 million, which includes the collection in the current year quarter of other receivables of \$6.7 million from the settlement agreement with Siemens Healthcare Diagnostics Inc., and a change in the net income of \$8.2 million.

Net cash used in investing activities in fiscal 2016 was approximately \$0.5 million as compared to \$0.3 million in the 2015 period, an increase of \$0.2 million. The increase in the 2016 period is primarily due to increased capital expenditures.

Net cash used in financing activities in fiscal 2016 was approximately \$0.1 million as compared to cash provided by financing activities of \$2.2 million in fiscal 2015. The decrease of \$2.3 million was due to proceeds from the issuance of common stock under the Controlled Equity Offering program of \$2.3 million in the 2015 period.

On June 7, 2013, the Company entered into a secured Revolving Loan and Security Agreement (the "Credit Agreement") among the Company and certain of its subsidiaries, with Enzo Therapeutics as a guarantor, and MidCap Financial Services, LLC (formerly Healthcare Finance Group, LLC). The Credit Agreement, which expires in December 2016, provides for borrowings against eligible US receivables, as defined, of the Clinical Labs and Life Sciences segments up to \$8.0 million at defined eligibility percentages and provides for additional borrowings of \$4.0 million for increased eligible assets. At October 31, 2015 and July 31, 2015 borrowings under the Credit Agreement related to the Clinical Labs and Life Sciences receivables aggregated \$3.0 million, with an additional availability of \$2.4 million as of October 31, 2015. As of October 31, 2015, the Credit Agreement was amended to add and redefine certain terms used in the Cash Burn covenant calculation, principally the elimination of capital expenditures from the calculation when Liquidity exceeds \$7.0 million. As of October 31, 2015, the Company is in compliance with the modified financial covenants. See Note 6 to the Consolidated Financial Statements herein for a further description of the Credit Agreement's terms, the amendment and financial covenants.

The Company continued to review all operating units to further reduce annual operating expenditures in fiscal 2016. While revenues and operating results at the Clinical Labs segment improved, revenues for the Life Sciences segment declined versus fiscal 2015, primarily due to foreign currency fluctuation. If revenues were to significantly decline, the segment could be required to record impairments of its intangible assets, which last occurred in fiscal 2012. The Company believes that its current cash and cash equivalents level, utilization of the Controlled Equity Offering program if necessary, as disclosed in Form 10-K Note 10 to the financial statements, which resulted in net proceeds of \$6.7 million during the fiscal year ended July 31, 2015, and available borrowings under the aforementioned Revolving Loan and Security Agreement disclosed in Note 6 to the financial statements herein are sufficient for its foreseeable liquidity and capital resource needs over the next twelve (12) months, although there can be no assurance that future events will not alter such view. Although there can be no assurances, in the event additional capital is required, the Company believes it has the ability to raise additional funds through equity offerings or other sources of funds. Our liquidity plans are subject to a number of risks and uncertainties, including those described in the Item 1A. "Risk Factors" section of this Form 10-K for the year ended July 31, 2015, some of which are outside our control. Macroeconomic conditions could limit our ability to successfully execute our business plans and therefore adversely affect our liquidity plans.

See our Form 10-K for the fiscal year ended July 31, 2015 for Forward Looking Cautionary Statements.

Contractual Obligations

There have been no material changes to our Contractual Obligations as reported in our Form 10-K for the fiscal year ended July 31, 2015.

Management is not aware of any material claims, disputes or settled matters concerning third party reimbursement that would have a material effect on our financial statements, except as disclosed in Note 13 to the Consolidated Financial Statement.

Off-Balance Sheet Arrangements

The Company does not have any "off-balance sheet arrangements" as such term is defined in Item 303(a)(4) of Regulation S-K.

Critical Accounting Policies

The Company's discussion and analysis of its financial condition and results of operations are based upon Enzo Biochem, Inc.'s consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. These estimates and judgments also affect related disclosure of contingent assets and liabilities.

On an on-going basis, we evaluate our estimates, including those related to contractual expense, allowance for uncollectible accounts, inventory, intangible assets and income taxes. The Company bases its estimates on experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Product revenues

Revenues from product sales are recognized when the products are shipped and title transfers, the sales price is fixed or determinable and collectability is reasonably assured.

Royalties

Royalty revenues are recorded in the period earned. Royalties received in advance of being earned are recorded as deferred revenues.

Revenues – Clinical laboratory services

Revenues from Clinical Labs are recognized upon completion of the testing process for a specific patient and reported to the ordering physician. These revenues and the associated accounts receivable are based on gross amounts billed or billable for services rendered, net of a contractual adjustment, which is the difference between amounts billed to payers and the expected approved reimbursable settlements from such payers.

The following table represents the clinical laboratory segment's net revenues and percentages by revenue category:

| Revenue category | Three months ended October 31, 2015 | | Three months ended October 31, 2014 | |
|-------------------|---|-------|---|-------|
| Third-party payer | \$9,695 | 57 % | \$8,713 | 55 % |
| Medicare | 2,996 | 18 | 3,222 | 20 |
| Patient self-pay | 3,239 | 19 | 2,664 | 17 |
| HMO's | 1,160 | 6 | 1,223 | 8 |
| Total | \$17,090 | 100 % | \$15,822 | 100 % |

The Company provides services to certain patients covered by various third-party payers, including the Federal Medicare program. Laws and regulations governing Medicare are complex and subject to interpretation for which action for noncompliance includes fines, penalties and exclusion from the Medicare programs. See Note 13 in the Notes to Consolidated Financial Statements.

Other than the Medicare program, one provider whose programs are included in the "Third-party payers" and "Health Maintenance Organizations" ("HMO's") categories represents approximately 29% and 26% of the Clinical Labs segment net revenue for the three months ended October 31, 2015 and 2014 respectively.

Contractual Adjustment

The Company's estimate of contractual adjustment is based on significant assumptions and judgments, such as its interpretation of payer reimbursement policies, and bears the risk of change. The estimation process is based on the experience of amounts approved as reimbursable and ultimately settled by payers, versus the corresponding gross amount billed to the respective payers. The contractual adjustment is an estimate that reduces gross revenue, based on gross billing rates, to amounts expected to be approved and reimbursed. Gross billings are based on a standard fee schedule we set for all third party payers, including Medicare, HMO's and managed care. The Company adjusts the contractual adjustment estimate quarterly, based on its evaluation of current and historical settlement experience with

payers, industry reimbursement trends, and other relevant factors.

The other relevant factors that affect our contractual adjustment include the monthly and quarterly review of: 1) current gross billings and receivables and reimbursement by payer, 2) current changes in third party arrangements and 3) the growth of in-network provider arrangements and managed care plans specific to our Company.

Our clinical laboratory business is primarily dependent upon reimbursement from third-party payers, such as Medicare (which principally serves patients 65 and older) and insurers. We are subject to variances in reimbursement rates among different third-party payers, as well as constant changes of reimbursement rates. Changes that decrease reimbursement rates or coverage would negatively impact our revenues. The number of individuals covered under managed care contracts or other similar arrangements has grown over the past several years and may continue to grow in the future. In addition, Medicare and other government healthcare programs continue to shift to managed care. These trends will continue to reduce our revenues.

During the three months ended October 31, 2015 and 2014, the contractual adjustment percentages, determined using current and historical reimbursement statistics, were 84.5% and 85.3%, respectively, of gross billings. The Company believes a decline in reimbursement rates or a shift to managed care or similar arrangements may be offset by the positive impact of an increase in the number of tests we perform. However, there can be no assurance that we can increase the number of tests we perform or that if we do increase the number of tests we perform, that we can maintain that higher number of tests performed, or that an increase in the number of tests we perform would result in increased revenue.

The Company estimates (by using a sensitivity analysis) that each 1% point change in the contractual adjustment percentage could result in a change in clinical laboratory services revenues of approximately \$1.1 million and \$1.0

million for the three months ended October 31, 2015 and 2014, respectively, and a change in the net accounts receivable of approximately \$0.6 million as of October 31, 2015.

Our clinical laboratory financial billing system records gross billings using a standard fee schedule for all payers and does not record contractual adjustment by payer at the time of billing. Therefore, we are unable to quantify the effect of contractual adjustment recorded during the current period that relate to revenue recorded in a previous period. However, we can reasonably estimate our monthly contractual adjustment to revenue on a timely basis based on our quarterly review process, which includes:

- an analysis of industry reimbursement trends;
- an evaluation of third-party reimbursement rates changes and changes in reimbursement arrangements with third-party payers;
- a rolling monthly analysis of current and historical claim settlement and reimbursement experience statistics with payers;
- an analysis of current gross billings and receivables by payer.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are reported at realizable value, net of allowances for doubtful accounts, which is estimated and recorded in the period of the related revenue.

The following is a table of the Company's net accounts receivable by segment. The Clinical Labs segment's net receivables are detailed by billing category and as a percent to its total net receivables. At October 31, 2015 and July 31, 2015, approximately 68% of the Company's net accounts receivable relates to its Clinical Labs business, which operates in the New York, New Jersey, and Eastern Pennsylvania medical communities.

The Life Sciences segment's accounts receivable, of which \$1.2 million or 29% and \$1.1 million or 28% represents foreign receivables as of October 31, 2015 and July 31, 2015, includes royalty receivables of \$0.1 million, as of October 31, 2015 and July 31, 2015, from Qiagen Corporation.

Net accounts receivable

Billing category

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

| | As of October 31, 2015 | | As of July 31, 2015 | |
|---------------------------|------------------------------|-------|------------------------|-------|
| Clinical Labs | | | | |
| Patient self-pay | \$4,350 | 49 % | \$3,213 | 39 % |
| Third party payers | 3,139 | 36 | 3,595 | 44 |
| Medicare | 1,012 | 12 | 1,081 | 13 |
| HMO's | 282 | 3 | 305 | 4 |
| Total Clinical Labs | 8,783 | 100 % | 8,194 | 100 % |
| Total Life Sciences | 3,980 | | 3,915 | |
| Total accounts receivable | \$12,763 | | \$12,109 | |

Changes in the Company's allowance for doubtful accounts are as follows:

| | October 31, 2015 | July 31, 2015 |
|---------------------------------|------------------------|------------------|
| Beginning balance | \$1,786 | \$2,142 |
| Provision for doubtful accounts | 704 | 2,284 |
| Write-offs, net | (604) | (2,640) |
| Ending balance | \$1,886 | \$1,786 |

For the Clinical Labs segment, the allowance for doubtful accounts represents amounts that the Company does not expect to collect after the Company has exhausted its collection procedures. The Company estimates its allowance for doubtful accounts in the period the related services are billed and reduces the allowance in future accounting periods based on write-offs during those periods. It bases the estimate for the allowance on the evaluation of historical experience of accounts going to collections and the net amounts not received. Accounts going to collection

include the balances, after receipt of the approved settlements from third party payers, for the insufficient diagnosis information received from the ordering physician which result in denials of payment, and our estimate of the uncollected portion of receivables from self-payers, including deductibles and copayments, which are subject to credit risk and patients' ability to pay.

As at October 31, 2015 and 2014, the Company recategorized to collections customers whose accounts receivable had been outstanding more than 210 days. The Company fully reserves through its contractual allowances amounts that have not been written off because the payer's filing date deadline has not occurred or the collection process has not been exhausted. The Company's collection experience on Medicare receivables beyond 210 days has been insignificant. The Company adjusts the historical collection analysis for recoveries, if any, on an ongoing basis.

The Company's ability to collect outstanding receivables from third party payers is critical to its operating performance and cash flows. The primary collection risk lies with uninsured patients or patients for whom primary insurance has paid but a patient portion remains outstanding. The Company also assesses the current state of its billing functions in order to identify any known collection or reimbursement issues in order to assess the impact, if any, on the allowance estimates, which involves judgment. The Company believes that the collectability of its receivables is directly linked to the quality of its billing processes, most notably, those related to obtaining the accurate patient information in order to bill effectively for the services provided. Should circumstances change (e.g. shift in payer mix, decline in economic conditions or deterioration in aging of receivables), our estimates of net realizable value of receivables could be reduced by a material amount.

Billing for laboratory services is complicated because of many factors, especially: the differences between our standard gross fee schedule for all payers and the reimbursement rates of the various payers we deal with, disparity of coverage and information requirements among the various payers, and disputes with payers as to which party is responsible for reimbursement.

The allowance for doubtful accounts as a percentage of total accounts receivable at October 31, 2015 and July 31, 2015 was 12.9%. During fiscal 2015, the contractual allowance applied to the Clinical Labs segment's patient self-pay revenues was increased based on collections trends, which has the effect of reducing the allowance for doubtful patient pay accounts receivable. We continue to improve our patient pay collection process by billing patients sooner and by giving past due accounts to collection agencies sooner.

The following table indicates the Clinical Labs aged gross receivables by payer group which is prior to adjustment to gross receivables for: 1) contractual adjustment, 2) fully reserved balances not yet written off, and 3) other revenue adjustments.

| As of October 31, 2015 | Total | % | Third Party Payers | % | Medicare Payers | % | Self Pay | % | HMO's | % |
|-------------------------------|--------------|----------|-----------------------------------|----------|----------------------------|----------|---------------------|----------|--------------|----------|
|-------------------------------|--------------|----------|-----------------------------------|----------|----------------------------|----------|---------------------|----------|--------------|----------|

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

| | | | | | | | | | | |
|------------------------|----------|------|----------|------|----------|------|---------|------|---------|------|
| 1-30 days | \$29,709 | 54 | \$18,151 | 50 | \$ 4,454 | 57 | \$3,328 | 47 | \$3,776 | 99 |
| 31-60 days | 6,272 | 11 | 3,773 | 10 | 684 | 9 | 1,798 | 25 | 17 | 1 |
| 61-90 days | 4,380 | 8 | 2,275 | 6 | 493 | 6 | 1,611 | 23 | 1 | — |
| 91-120 days | 3,854 | 7 | 2,899 | 8 | 495 | 6 | 458 | 6 | 2 | — |
| 121-150 days | 2,673 | 5 | 2,362 | 7 | 320 | 4 | (9) | — | — | — |
| Greater than 150 days* | 8,405 | 15 | 7,040 | 19 | 1,413 | 18 | (47) | (1) | (1) | — |
| Totals | \$55,293 | 100% | \$36,500 | 100% | \$ 7,859 | 100% | \$7,139 | 100% | \$3,795 | 100% |

| As of July 31, 2015 | Total | % | Third Party Payers | % | Medicare Payers | % | Self Pay | % | HMO's | % |
|-------------------------|----------|------|--------------------|------|-----------------|------|----------|------|---------|------|
| 1-30 days | \$28,157 | 53 | \$17,527 | 50 | \$ 4,048 | 52 | \$2,991 | 47 | \$3,591 | 95 |
| 31-60 days | 6,650 | 13 | 4,109 | 12 | 802 | 10 | 1,718 | 27 | 21 | 1 |
| 61-90 days | 4,191 | 8 | 2,313 | 7 | 578 | 7 | 1,276 | 20 | 24 | 1 |
| 91-120 days | 3,651 | 7 | 2,534 | 7 | 604 | 8 | 474 | 7 | 39 | 1 |
| 121-150 days | 2,856 | 4 | 2,426 | 7 | 399 | 5 | (3) | 0 | 34 | 1 |
| Greater than 150 days** | 7,187 | 14 | 5,878 | 17 | 1,329 | 18 | (40) | -1 | 20 | 1 |
| Totals | \$52,692 | 100% | \$34,787 | 100% | \$ 7,760 | 100% | \$6,416 | 100% | \$3,729 | 100% |

* Total includes \$4,822 fully reserved over 210 days as of October 31, 2015.

**Total includes \$4,072 fully reserved over 210 days as of July 31, 2015.

Income Taxes

The Company accounts for income taxes under the liability method of accounting for income taxes. Under the liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The liability method requires that any tax benefits recognized for net operating loss carry forwards and other items be reduced by a valuation allowance where it is not more likely than not the benefits will be realized in the foreseeable future. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under the liability method, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

It is the Company's policy to provide for uncertain tax positions and the related interest and penalties based upon management's assessment of whether a tax benefit is more likely than not to be sustained upon examination by tax authorities. To the extent the Company prevails in matters for which a liability for an unrecognized tax benefit is established or is required to pay amounts in excess of the liability, the Company's effective tax rate in a given financial statement period may be affected.

Inventory

The Company values inventory at the lower of cost (first-in, first-out) or market. Work-in-process and finished goods inventories consist of material, labor, and manufacturing overhead. Write downs of inventories to market value are based on a review of inventory quantities on hand and estimated sales forecasts based on sales history and anticipated future demand. Unanticipated changes in demand could have a significant impact on the value of our inventory and require additional write downs of inventory which would impact our results of operations.

Goodwill and Intangible Assets

Goodwill represents the excess of the cost of an acquisition over the fair value of the net assets acquired. Intangible assets (exclusive of patents), arose primarily from acquisitions, and primarily consist of customer relationships, trademarks, licenses, and website and database content. Finite-lived intangible assets are amortized according to their estimated useful lives, which range from 4 to 15 years. Patents represent capitalized legal costs incurred in pursuing patent applications. When such applications result in an issued patent, the related capitalized costs are amortized over a ten year period or the life of the patent, whichever is shorter, using the straight-line method. The Company reviews its issued patents and pending patent applications, and if it determines to abandon a patent application or that an issued patent no longer has economic value, the unamortized balance in deferred patent costs relating to that patent is immediately expensed.

The Company tests goodwill and long-lived assets annually as of the first day of the fourth quarter, or more frequently if indicators of potential impairment exist. In assessing goodwill and long-lived assets for impairment, the Company has the option to first perform a qualitative assessment to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the Company determines that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, the Company is not required to perform any additional tests in assessing goodwill and long-lived assets for impairment. However, if the Company concludes otherwise or elects not to perform the qualitative assessment, then it is required to perform the first step of a two-step quantitative impairment review process. The first step of the quantitative impairment test requires the identification of the reporting units and comparison of the fair value of each of these reporting units to their respective carrying value. If the carrying value of the reporting unit is less than its fair value, no impairment exists and the second step is not performed. If the carrying value of the reporting unit is higher than its fair value, the second step must be performed to compute the amount of the goodwill impairment, if any. In the second step, the impairment is computed by comparing the implied fair value of the reporting unit goodwill with the carrying amount of that goodwill. If the carrying amount of the reporting unit goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized for the excess

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk from changes in foreign currency exchange rates resulting from acquisitions with foreign locations (See Item 1A. Risk Factors section of the Form 10-K for the fiscal year ended July 31, 2015) that could impact our results of operations and financial position. We do not currently engage in any hedging or market risk management tools.

Foreign Currency Exchange Rate Risk

The financial reporting of our non-U.S. subsidiaries is denominated in currencies other than the U.S. dollar. Since the functional currency of our non-U.S. subsidiaries is the local currency, foreign currency translation adjustments are accumulated as a component of accumulated other comprehensive income in stockholders' equity. Assuming a hypothetical increase of 10% in the value of the U.S. dollar versus foreign currencies at October 31, 2015, our assets and liabilities would decrease by \$0.5 million and \$0.1 million, respectively, and our net sales and net earnings (loss) would decrease by \$0.9 million and \$0.3 million, respectively, on an annual basis.

We also maintain intercompany balances and loans with subsidiaries in different local currencies. These amounts are at risk of foreign exchange losses if exchange rates fluctuate. Assuming a hypothetical increase of 10% in the value of the U.S. dollar versus foreign currencies, our pre-tax earnings (loss) would be unfavorably impacted by approximately \$0.9 million on an annual basis.

Interest Rate Risk

We are exposed to interest rate risk with our variable rate Credit Agreement which bears interest at the three month LIBOR with a floor of 1.25% plus 4% per annum. A 3% change in the LIBOR rate would impact our interest expense by \$0.1 million.

As of October 31, 2015, we have fixed interest rate financing on transportation and equipment leases.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, the Company's management conducted an evaluation (as required under Rules 13a-15(b) and 15d-15(b) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) of the Company's "disclosure controls and procedures" (as such term is defined under the Exchange Act), under the supervision and with the participation of the principal executive officer and the principal financial officer. Based on this evaluation, the principal executive officer and the principal financial officer concluded that the Company's disclosure controls and procedures are effective as of the end of the period covered by this report. Notwithstanding the foregoing, a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that it will detect or uncover failures within the Company to disclose material information otherwise required to be set forth in the Company's periodic reports.

(b) Changes in Internal Controls over Financial Reporting

There was no change in the Company's internal controls over financial reporting during the fiscal quarter covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

There have been no other material developments with respect to previously reported legal proceedings discussed in the annual report on Form 10-K for the fiscal year ended July 31, 2015 filed with the Securities and Exchange Commission, other than as noted in Note 13 to the Consolidated Financial Statements as of October 31, 2015.

Item 1A. Risk Factors

There have been no material changes from the risk factors disclosed in Part 1, Item 1A of the Company’s Annual Report on Form 10-K for the fiscal year ended July 31, 2015.

Item 6. Exhibits

| Exhibit No. | Exhibit |
|--------------------|--|
| 10 (t) | Amendment to Revolving Loan and Security Agreement among the Enzo Biochem, Inc., Enzo Clinical Labs, Inc., Enzo Life Sciences, Inc., Axxora, LLC and Enzo Realty, LLC as borrowers, and Enzo Therapeutics, Inc. as a guarantor, and HFG Healthco–4 Trust as Lender |
| 31.1 | Certification of Elazar Rabbani, Ph.D. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of Barry Weiner pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of Elazar Rabbani, Ph.D. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2 | Certification of Barry Weiner pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS* | XBRL Instance Document |
| 101.SCH* | XBRL Taxonomy Extension Schema Document |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF* | XBRL Taxonomy Extension Definitions Linkbase Document |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase Document |

*XBRL (Extensible Business Reporting Language) information is being furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ENZO BIOCHEM, INC.
(Registrant)

Date: December 8, 2015 by: /s/ Barry Weiner
President, Chief Financial Officer, Principal Accounting Officer, Treasurer and Director

28